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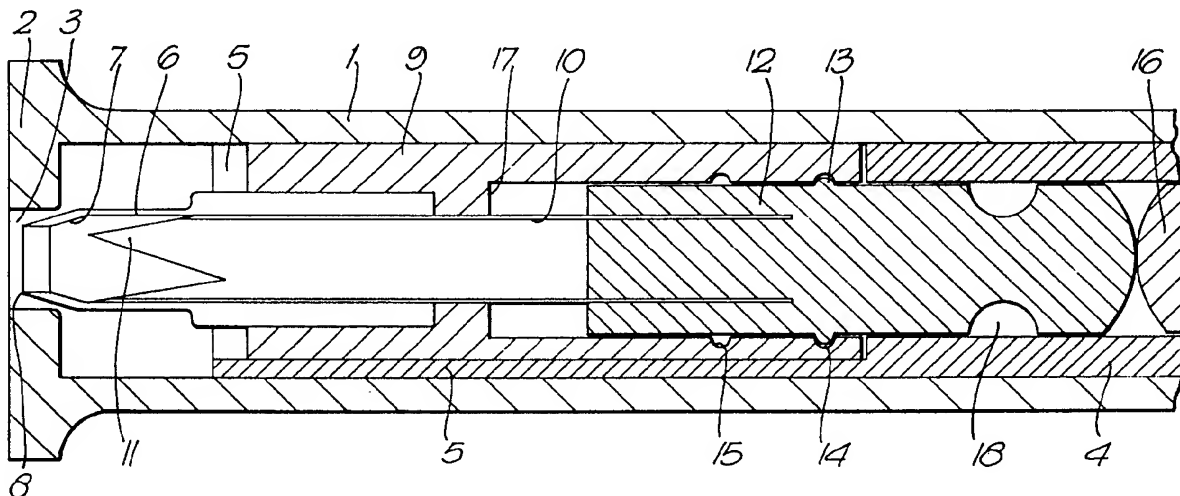
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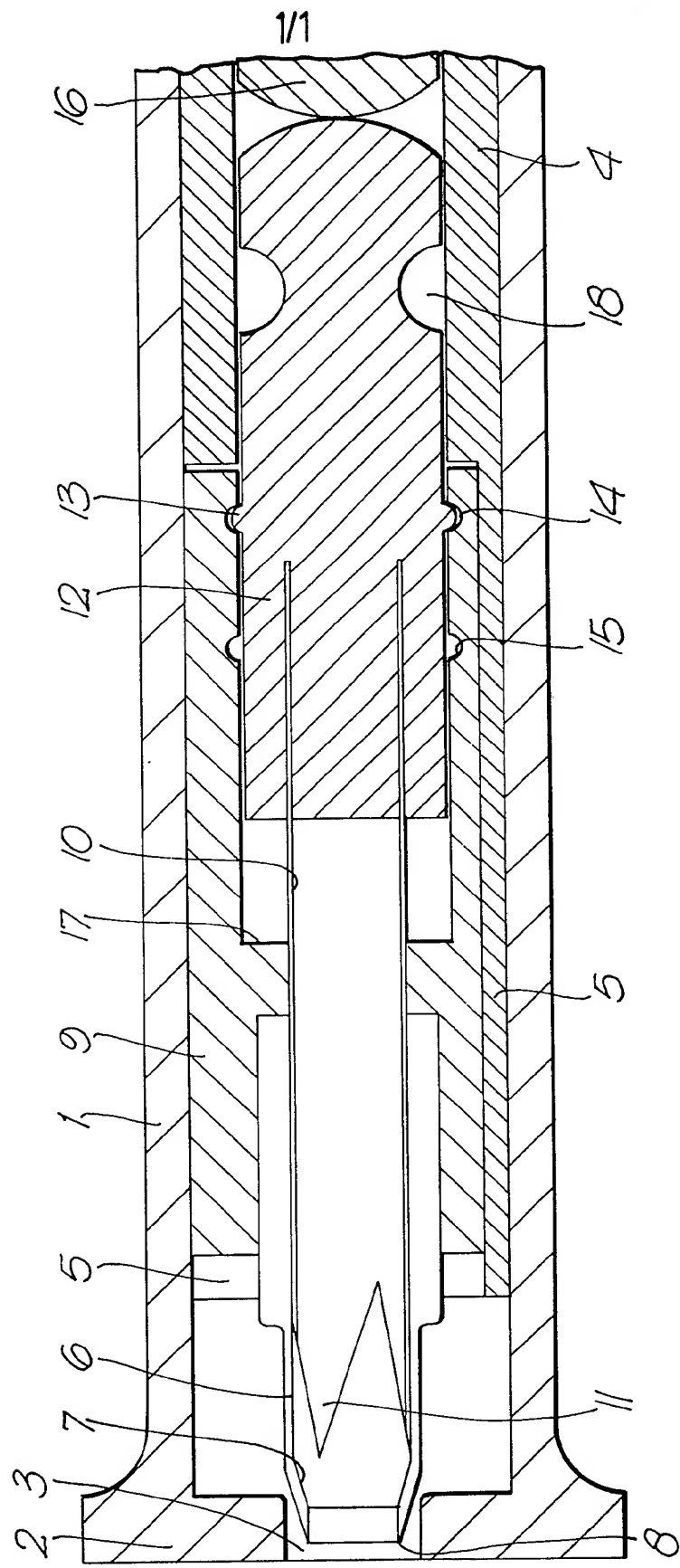
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Selected US specifications from IPC sub-class A61B

(54) **Tissue sampler for biopsy**

(57) An instrument for taking a tissue sample for biopsy has a housing (1), an outer tube (6) with an annular cutting edge (8) which is advanceable through a hole (3) in the housing to cut a core sample, and an inner tube (10) which is then advanceable so that flexible tangs (11) are cammed inwards by surface 7 to grasp the inner end of the core sample and sever it. Projection 13 engages detents 14 or 15 to retain tube 10 in position.





SPECIFICATION

Tissue sampler

- 5 The invention relates to an instrument for taking a sample of tissue for biopsy purposes. Conventional instruments, such as those for taking a sample of cervix for testing for cancer, precancer or other benign conditions
- 10 comprise a pair of jaws, which are remotely manipulated on the end of a probe. The jaws are used to take a bite of tissue and provide a pair of U-shaped cutting surfaces which shear the tissue as the jaws are closed. It is
- 15 difficult to manipulate the instrument accurately to make a clean bite of a predetermined volume of tissue, and the action of the jaws inevitably squeezes the tissue before the shearing is effected. The result is that the
- 20 sample will be of indeterminate size and shape, and, when the jaws have been opened to recover the sample, it will expand so that its orientation relatively to the surface of the tissue body, from which it was taken, is uncertain. When testing for cervical cancer, it is
- 25 important to be able to recognise an interface between outer and inner layers of cells as the biopsy involves recognising migration of cells across the interface. It follows that in many
- 30 samples the interface is unrecognisable and a new sample has to be obtained, with a commensurate cost in terms of wasted time and, from the point of view of the patient, possible dangerous diagnostic delay.
- 35 In accordance with the present invention, an instrument for taking a tissue sample for biopsy comprises first and second coaxial, relatively axially slidable, tubular elements, the first element terminating in an annular knife
- 40 edge and the second element terminating in at least one substantially axially projecting flexible tang which cooperates with camming means, the arrangement being such that a tissue core sample may be taken by advancing the first
- 45 element axially into the tissue, then advancing the second element relatively to the first element around the core sample so that the tang is flexed inwards by the camming means to grasp the inner end of the core sample, and
- 50 then withdrawing the tubular elements with the core sample from the tissue.
- With this instrument a core sample of tissue, of predetermined size and shape may be cut cleanly. In a case of a sample of cervix,
- 55 the core will be cut through the outer and inner cell layers and the important interface will be clearly recognisable at a transverse plane partway along the core.
- The second element could terminate in a
- 60 ring of tapering tangs which are flexed together by the camming means so that the tangs substantially fully enclose the inner core sample. In this case the tangs will effectively separate the inner end of the core sample
- 65 from the body of tissue and to assist this the

tangs should have sharp edges so that they will easily cut through the tissue. Alternatively there may be a single tang, in which case if the second element is rotatable and the tang

70 has a sharp edge the single tang will sever the inner end of the core sample from the body of tissue as the second element is rotated, e.g. manually by a handpiece connected to the second element.

- 75 The second element is preferably mounted inside the first element and the camming means may then be provided by a frustotapered inner surface of the tip of the first element adjacent to the annular knife edge. If the
- 80 inner cross section of the second element is at least slightly larger than the cross section of the annular knife edge, there will then be sufficient room for the second element to be advanced around the core sample relatively to
- 85 the first element without disturbing the core sample.

Detent or other means are preferably provided for retaining the second element in its advanced position relatively to the first element so that the core sample is retained by the second element during withdrawal of the instrument from the tissue body.

- The two elements are preferably slidable in a housing of a cutting head, the housing having an end surface for abutting the tissue body, and, in the end surface, a hole for projection of the elements into the tissue body to cut the sample.
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- Some means are preferably provided for enabling rotation of the first element when it is advanced into the tissue body, so that the annular knife edge makes a clean cut around the core sample. The rotation may be automatic as the first element is advanced, or
- 100 manual, e.g. by manipulation of a handpiece connected to the first element.
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When the instrument is used to take a sample from within a body of a patient, for example a cervical sample, the elements will

110 be mounted on the end of a probe having means at its remote end for manipulating the axial, and, when provided, also the rotary, movements of the elements.

- The elements may form a disposable part removably mounted, e.g. in a cutting head housing on the end of a probe, so that the core sample may be sent to the laboratory retained within the elements. There will then be no disturbance of the sample between taking the sample from the patient and the laboratory testing.
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One example of an instrument constructed in accordance with the present invention is illustrated diagrammatically in the accompanying drawing, which is an axial section through a cutting head of the instrument.

- The cutting head has a housing 1, which forms an extension of an outer sheath of a probe, and which has an end wall 2 formed with a central opening 3. Within the outer
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- 130

sheath is an inner sheath 4, terminating in an open topped holder 5 of circular external and square internal cross section. A first metal tubular element 6, having a frustoconical tip 7 terminating in an annular knife edge 8 is moulded in a plastics body 9 of square cross section and removably seated within the holder 5. Coaxially slidable within the element 6 and body 9 is a second metal tubular element 10 terminating in a ring of pointed tangs 11 and moulded in a plastics body 12. The body 12 has an annular dimple 13 which cooperates with one or other of two annular grooves 14 and 15 in the body 9. A pusher 16 extends along the probe within the sheaths and abuts the end of the body 12.

In use, the probe is inserted, cutting head end first, through, for example a vagina if a cervical sample is to be taken, until the end surface 2 abuts the cervix. The inner sheath 4 is then advanced and rotated, by manipulating a handpiece at the remote external end of the probe, so that the element 6 is advanced through the opening 3 into the cervical issue. This continues until the end of the holder 5 abuts the inner surface of the end wall 2. The element 10 is carried along with the element 6 owing to the cooperation between the dimple 13 and the groove 14. As a result a core of cut tissue will extend into the elements 6 and 10. The pusher 16 is then advanced relatively to the inner sheath 4, so that the dimple 13 rides out of the groove 14 and the element 10 is advanced into the tip of the element 6. The inner frustoconical surface of the tip 7 deflects the tangs 11 inwards so that they cut through and grasp the inner end of the core, separating the core completely from the cervical tissue. This continues until the tip of the body 12 abuts a shoulder 17 in the body 9, and the dimple 13 rides into the groove 15. The whole cutting head is then withdrawn from the patient. The inner sheath 4 and holder 5 are then removed from within the outer sleeve, or at least from within the housing 1, whereupon the elements 6 and 10, together with their associated bodies 9 and 12, are removed from the holder 5. At the laboratory the element 10, together with the core sample, may be removed from the element 6 and body 9 by withdrawing the body 12 utilizing a tool engaging an annular groove 18, the dimple 13 riding out of the groove 15 and past the groove 14.

In a modification (not shown) there is a single tang 11 and the pusher 16 is fixed to the body 12. The remote end of the pusher carries a handpiece by means of which the body 12 and tang can be advanced and rotated.

CLAIMS

1. An instrument for taking a tissue sample for biopsy, the instrument comprising first and second coaxial, relatively axially slidable, tubular elements, the first element terminating in

an annular knife edge and the second element terminating in at least one substantially axially projecting flexible tang which cooperates with camming means, the arrangement being such that a tissue core sample may be taken by advancing the first element axially into the tissue, then advancing the second element relatively to the first element around the core sample so that the tang is flexed inwards by the camming means to grasp the inner end of the core sample, and then withdrawing the tubular elements with the core sample from the tissue.

2. An instrument according to claim 1, in which the second element is mounted inside the first element and the camming means is provided by a frustotapered inner surface of the tip of the first element adjacent to the annular knife edge.

3. An instrument according to claim 1 or claim 2, in which means are provided for retaining the second element in its advanced position relatively to the first element so that the core sample is retained by the second element during withdrawal of the instrument from the tissue body.

4. An instrument according to any one of the preceding claims, in which the two elements are slidable in a housing of a cutting head, the housing having an end surface for abutting the tissue body, and, in the end surface, a hole for projection of the elements into the tissue body to cut the sample.

5. An instrument according to any one of the preceding claims, in which means are provided for enabling rotation of the first element when it is advanced into the tissue body, so that the annular knife edge makes a clean cut around the core sample.

6. An instrument according to any one of the preceding claims, in which the elements form a disposable part removably mounted in a cutting head housing on the end of a probe, so that the core sample may be sent to the laboratory retained within the elements.

7. An instrument for taking a tissue sample, substantially as described with reference to the accompanying drawing.

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